GOVERNMENT OF INDIA
ATOMIC ENERGY
LOK SABHA

UNSTARRED QUESTION NO:1740
ANSWERED ON:04.05.2016
Atomic Material
Singh Shri Bhola

Will the Minister of ATOMIC ENERGY be pleased to state:

(a)the details regarding radio sterilisation;

(b)whether the Government has done any impact assessment of radio sterilisation for the future benefit of atomic energy; and

(c)if so, the details thereof and if not, the reasons therefor?

Answer

THE MINISTER OF STATE FOR PERSONNEL, PUBLIC GRIEVANCES & PENSIONS AND PRIME MINISTER'S OFFICE (Dr. JITENDRA SINGH) :

(a)Radiation Sterilisation is a cold process that uses gamma radiation for sterilisation of Healthcare Products. Controlled gamma energy which is released by radioisotope such as Cobalt-60 is used for sterilisation. Cobalt-60 is most preferred radioisotope as it is readily available from single nuclear reaction in reactor and also cost effective. Gamma radiation is characterised by deep penetration and kills microorganism by destroying DNA structure. The process is suitable for Industrial scale sterilisation. Radiation dose of 25 kGy (2.5 Mrad) is officially accepted dose for sterilisation of healthcare products. Delivery of dose to the products is measured by dosimeter. Radiation sterilised products are acceptable by Food & Drug Administration (FDA).

Advantages and Benefits of Radiation Sterilisation

(a)Products of any shape can be sterilised because powerful gamma rays can penetrate right through the package and the product.

(b)Being a cold process, heat sensitive plastic medical devices and pharmaceutical products can safely be sterilised.

(c)Flexibility in packaging, as the products can be packed individually in sealed bags and sterilised in the fully packaged form.

(d)Since sterilisation is effected after final packaging, product sterility is retained indefinitely provided the package is undamaged.

(e)Radiation Sterilisation enlarges the market for ready to use pre-packaged products. The process does not result into residual toxicity of any form in the product.

(f)Products sterilised by this process do not become radioactive and are safe for use.

(g)Presently out of 18 operating plants in Government/Semi-Government/Private/Co-operative sectors, around 13 are also engaged in sterilisation of medical products.
Major components of a Radiation Sterilisation Plant

(i) A source of gamma radiation (Cobalt-60)
(ii) A radiation processing cell (irradiation cell)
(iii) Product conveyors and control mechanisms
(iv) Safety devices and interlocks

A Gamma Radiation Processing Facility is licensed by Atomic Energy Regulatory Board (AERB) and Local Food & Drug Administration (FDA).
High energy Electron Beam (EB) and X-ray machines are also used nowadays for this purpose. The major difference in gamma radiation and EB lies in their penetration powers, where gamma radiations can penetrate deep inside the products the electron beams do not have as good penetration power.

Though X-ray have comparable penetration power to gamma radiation at suitable energy range but they are not yet very popular.

(b)Board of Radiation and Isotope Technology (BRIT)/Department of Atomic Energy (DAE) has not carried out any impact assessment studies independently for Radiation Sterilisation of healthcare products.

(c)BRIT/DAE had setup a radiation sterilisation plant 'ISOMED' which is in operation since 1974 for sterilisation of medical products. Technology has been found to be effective, reliable and acceptable among users. Later two more Radiation Processing Plants one at

BRIT, Vashi Complex, Navi Mumbai and other at Lasalgaon near Nashik were set up for radiation processing of food and allied products. Both these plants are operating and users of this radiation technology are regularly increasing. In view of this BRIT has not carried out any impact study independently. However, it is promoting setting up of commercial radiation processing plants and so far 15 such plants are commissioned in Government/Semi-Government/Private/Co-operative Sectors excluding 3 plants of BRIT/DAE. Thus, the use of this technology is found to be acceptable.

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